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Datasheet for the decision of 6 September 2023

Case Number: T 2047/20 - 3.2.02

Application Number: 06707783.4

Publication Number: 1841493

IPC: A61M37/00

Language of the proceedings: EN

Title of invention:
APPLICATOR FOR INSERTING AN IMPLANT

Patent Proprietor:
Merck Sharp & Dohme B.V.

Opponent:
Holme Patent A/S

Relevant legal provisions:
EPC Art. 56, 83, 123(2)

Keyword:
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendments - added subject-matter (no)

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Case Number: T 2047/20 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 September 2023

Appellant: (Opponent)	Holme Patent A/S Valbygårdsvej 33 2500 Valby (DK)
Representative:	Holme Patent A/S Valbygårdsvej 33 2500 Valby (DK)
Respondent: (Patent Proprietor)	Merck Sharp & Dohme B.V. Waarderweg 39 2031 BN Haarlem (NL)
Representative:	Merck Sharp & Dohme LLC 120 Moorgate London EC2M 6UR (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 22 October 2020 concerning maintenance of the European Patent No. 1841493 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	Y. Podbielski

Summary of Facts and Submissions

I. This appeal lies from the interlocutory decision of the Opposition Division to maintain the contested patent in amended form on the basis of auxiliary request 2 filed during the oral proceedings before the Opposition Division on 28 September 2020 ("auxiliary request 2").

II. In its decision, the Opposition Division held that the invention as claimed in that request was sufficiently disclosed, and that the subject-matter of claim 1 of that request did not include added subject-matter and involved an inventive step over each of documents D1, D4, D5 and D6, even taking into account the common general knowledge and documents D2 or D3; D1-D6 being the following documents:

D1 WO 99/33512 A2
D2 WO 2004/026106 A2
D3 WO 98/13091 A1
D4 EP 0 858 813 A2
D5 US 5,906,599
D6 WO 2004/089458 A1

III. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

IV. The respondent (patent proprietor) requested that the patent be maintained on the basis of auxiliary request 2, i.e. that the appeal be dismissed; alternatively, that the patent be maintained on the basis of auxiliary request 3 filed with its submission of 28 July 2020, or on the basis of one of auxiliary

requests 4 and 5 filed with its reply to the appellant's statement of grounds of appeal.

V. The Board summoned the parties to oral proceedings and, in its communication under Article 15(1) RPBA 2020, expressed its preliminary view that the appeal was likely to be dismissed.

VI. By letter dated 1 June 2023, the appellant withdrew its request for oral proceedings and announced that it would not attend the scheduled oral proceedings. The Board therefore cancelled the oral proceedings.

VII. Claim 1 of auxiliary request 2 ("claim 1") reads as follows:

"*Applicator (1) for inserting an implant, in particular a rod-like implant (2) containing an active substance, under the skin of a human or animal, comprising*

a housing (3),

a cannula (6), fixed to a cannula holder (9), which is slidably received inside the housing (3),

an implant (2) accommodated inside the cannula (6) and/or the cannula holder (9),

a protective cover (7) for the cannula (6), and

a mechanism (22, 23, 7) which, at least after the cover (7) has been removed from the cannula (6), secures the implant (2) inside the cannula (6) and/or the cannula holder (9),

characterised in that

the mechanism (22, 23, 7) disengages the implant (2) during insertion of the cannula (6) or after the cannula (6) has been inserted and

wherein the mechanism (22, 23, 7) comprises a lever (22) extending along at least part of the cannula (6),

which lever (22) is rotatable and/or flexible between a first position wherein the implant (2) is secured inside the cannula (6) and/or the cannula holder (9) and a second position wherein the implant (2) is disengaged and

wherein the cannula (6) and/or the cannula holder (9) comprise an opening (30) which allows access to the implant (2), and the lever (22) comprises a protrusion (23) in register with this opening (30),

wherein the lever (22) is biased towards the cannula (6) and/or the cannula holder (9) such that the protrusion (23) urges the implant (2) against the inner wall of the cannula (6) or the cannula holder (9) and

the applicator is configured such that when the cannula (6) is inserted under the skin of a patient, skin on top of the cannula (6) lifts the lever (22) to such an extent that contact between the protrusion (23) and the implant (2) is removed thereby disengaging the implant."

VIII. The appellant's arguments relevant for this decision can be summarised as follows.

Sufficiency of disclosure

The contested patent as amended according to auxiliary request 2 contemplated a number of different embodiments which were insufficiently disclosed. Even using common general knowledge, a person skilled in the art would not be able to perform the invention over the whole area claimed without undue burden.

Firstly, claim 1 defined that the mechanism could alternatively disengage the implant "after the cannula has been inserted". The patent specified (see claim 1 and paragraph [0035] of the description) that the

disengagement of the protrusion from the implant resulted from the movement of the cannula as the latter was inserted into the skin, with the skin pushing the lever upwards. However, the patent was silent on any mechanism by which disengagement would occur when the cannula was no longer inserted into the skin, for example after a delay of a few seconds or a few minutes after the insertion of the cannula had been completed. In fact, this was not possible without a further, undisclosed means for lifting the lever.

Moreover, simply disengaging the protrusion from the implant was not sufficient to release the implant from the applicator. The lever had to be lifted to the extent that the protrusion was completely clear of the opening in the cannula, otherwise the cannula could not be retracted into the housing and the implant expelled. However, claim 1 did not require this and therefore encompassed non-functional embodiments, so that the problem was not solved over the entire scope of the claims.

Secondly, claim 1 specified that the implant could alternatively be accommodated inside the cannula holder instead of the cannula. This might indeed be possible since the cannula holder was an extension of the cannula. However, the person skilled in the art was left without any guidance as to how and where, in this case, the opening through which the protrusion of the lever was to engage the implant could be located in the cannula holder, and how to ensure that the lever could be lifted by the skin on top of the cannula to disengage the implant. In particular, the two embodiments shown in the drawings could not be simply adapted to function with the opening arranged in the cannula holder.

Thirdly, claim 1 specified that the lever was "rotatable and/or flexible" between a first position in which the implant was secured, and a second position in which the implant was disengaged. This defined three combinations for the lever: rotatable, flexible and rotatable, and flexible. However, the patent did not discuss any of these embodiments in detail. In particular, it was not clear how, when and/or to what extent the lever would begin to move, or which flexible material would provide the required properties.

Added subject-matter

Compared to claim 1 as originally filed, claim 1 included the additional feature that the cannula holder was "slidably received inside the housing". This feature, originally disclosed on page 7, lines 10-15, was inextricably linked to the further features that the applicator comprised two half-shells provided with two parallel and longitudinal guides and that the cannula holder was provided with corresponding longitudinal grooves. However, these further features had been omitted from claim 1. The subject-matter of claim 1 was therefore based on an inadmissible intermediate generalisation, in breach of Article 123(2) EPC.

Claim 1 also failed to recite the actuator 8 for causing the cannula holder to slide inside the housing and the rod 21 for expelling the implant from the cannula. The omission of these features also constituted an inadmissible intermediate generalisation. Accordingly, the sliding of the cannula holder inside the housing of the claimed applicator could be achieved by other undisclosed means, such as a

motor or a spring-loaded element, and similarly, claim 1 encompassed other embodiments in which the implant was not expelled at all or was expelled by other means, such as air pressure. Also for these reasons, the subject-matter of claim 1 extended beyond the content of the application as originally filed.

Inventive step

The subject-matter of claim 1 did not involve an inventive step starting from each of D1, D4, D5 and D6.

All of these documents indeed disclosed an applicator for inserting an implant from which the claimed applicator differed on account of the specific mechanism for engaging and disengaging the implant, based, *inter alia*, on a lever having a protrusion and on an *ad hoc* opening through which the protrusion could engage the implant, the lever being configured such that, when the cannula was inserted under the skin, skin on top of the cannula lifted the lever to such an extent that contact between the protrusion and the implant was removed, thereby disengaging the implant. This mechanism, however, was not inventive in view of the common general knowledge, for example as represented by D2, and D3.

Starting from D1

The term "lever" in the contested patent merely referred to a displacement means which could be placed in a first and a second position. Thus, the actuator 28 in the applicator of D1, which was slidable between two positions (Figures 4 and 5), constituted a lever. The applicator of D1 also included a protrusion for engaging the implant, formed by a portion of the

cannula which was permanently deformed inwards, reducing the internal diameter of the cannula (page 13, lines 8-14).

The applicator of claim 1 therefore differed from the applicator of D1 in that the protrusion for engaging the implant was located on the lever and engaged the implant through an opening in the cannula, and in that the applicator was configured such that when the cannula was inserted under the skin of a patient, skin on top of the cannula lifted the lever to such an extent that contact between the protrusion and the implant was removed, thereby disengaging the implant.

Faced with the technical problem of providing an alternative applicator for inserting an implant, the person skilled in the art starting from D1 would have been motivated to search for an improved retention means.

The provision of a protrusion in communication with an opening for engaging a part of a device and disengaging said device by moving the protrusion out of the opening was known from a number of everyday products, such as tent poles, pencils or snap-fittings. Such a retention mechanism was therefore common general knowledge. A similar mechanism was also disclosed in D2 in the context of another applicator for delivering an implant (Figure 15, paragraph [0072]), in which an outer retention means (O-ring 302) extended through an opening in the cannula and was in frictional contact with an implant 301 positioned therein.

In order to provide an alternative/improved engagement/ disengagement mechanism, the person skilled in the art would then have consulted D3, which described an

applicator having a penetration guide 7 (Figures 1-3). By engaging with the patient's skin, this guide ensured that the cannula 2 was inserted under the skin at the correct penetration depth. The person skilled in the art would have understood that such a penetration guide could also be used in the applicator of D1. In combination with the common general knowledge or D2, this would have led the person skilled in the art starting from D1 to a solution falling within the scope of claim 1 in an obvious manner.

Starting from D4

The applicator of D4 comprised a retention mechanism (tailpiece 11) which secured the implant 6 inside the cannula at least after removal of the cover from the cannula, and which disengaged the implant during or after insertion of the cannula (column 5, lines 31-38; Figure 1). The sleeve 15 constituted a lever (column 3, lines 32-53; Figure 1), which ensured the desired penetration depth of the implant.

In view of D3, the person skilled in the art would obviously have modified the construction of D4 and used common general knowledge and/or D2 to modify the retention mechanism so that it used a projection and an opening to engage/disengage an implant in the cannula depending on whether or not skin was present on top of the cannula. The person skilled in the art starting from D4 would thus have arrived at a solution according to claim 1 without inventive skill.

Starting from D5

The applicator of D5 was also adapted for inserting an implant (column 5, lines 49-52). It included a

mechanism (outer tube 102) which, at least after the (implicitly disclosed) cover had been removed from the cannula 104, secured the implant 100 inside the cannula (column 4, lines 18-20), and wherein the mechanism disengaged the implant after the cannula had been inserted (column 4, lines 28-32 and Figure 4, indicating that item 102 was retracted after the cannula had been inserted). The cannula 104 had an opening which allowed access to the implant (Figure 4). The outer tube was in register with this opening and was biased towards the cannula (Figure 4).

In D5, the projection for engaging the implant was not located on the actuator, but was part of the cannula (cannula notch 104b). However, it would have been obvious to the person skilled in the art to implement the penetration guide 7 of D3 in the applicator of D5 and to arrange a protrusion on that penetration guide in order to ensure that when the device of D5 was inserted under the skin, the protrusion would disengage the cannula notch of D5 - a feature well known in the art as discussed for D1 - and thereby disengage the implant. In this way, the person skilled in the art starting from D5 would have arrived at the claimed applicator without an inventive step.

Starting from D6

It would also have been obvious to the person skilled in the art to incorporate the penetration guide 7 of D3 into the applicator of D6 and to provide a protrusion on the penetration guide to ensure that when the cannula of D6 was inserted under the skin, the protrusion would disengage the cannula - a feature well known in the art as discussed for example in D1 - and thereby disengage the implant. In this way, the person

skilled in the art starting from D6 would also have arrived at the claimed applicator without an inventive step.

IX. The respondent's arguments relevant for this decision can be summarised as follows.

Sufficiency of disclosure

The invention to which the contested patent as amended according to auxiliary request 2 related was sufficiently disclosed. With the technical information from the figures, together with the detailed description of the two disclosed embodiments, a person skilled in the art would have been able to construct an applicator as defined in claim 1 without undue burden.

Added subject-matter

Claim 1 did not include any added subject-matter.

Inventive step

The subject-matter of claim 1 involved an inventive step starting from each of D1, D4, D5 and D6.

The subject-matter of claim 1 differed from the applicators known from these documents at least by the specific mechanism based on a skin-actuated lever having a protrusion in register with an opening provided in the cannula or cannula holder, by which the implant was secured in the cannula and then disengaged during the insertion of the cannula or after the cannula had been inserted.

The technical problem to be solved starting from each of these documents was to provide an applicator enabling an implant to be secured in the cannula and then inserted without being damaged.

The person skilled in the art would not have arrived at the claimed mechanism in an obvious manner, even taking into account the common general knowledge, D2 and D3. In particular, D2 and D3 disclosed devices which were designed for different purposes and did not teach or suggest the claimed mechanism.

Reasons for the Decision

1. Subject-matter of the contested patent

1.1 The contested patent concerns an applicator for inserting a implant under the skin of a subject, such as a contraceptive rod-like implant (paragraph [0001] of the patent specification). An example of an applicator according to claim 1 is illustrated in Figures 6 to 8, reproduced below.

This applicator comprises a housing, a cannula (6) fixed to a cannula holder (9), which is slidably received inside the housing, and a removable protective cover (7). Before use, a rod-like implant (2) is accommodated within the cannula, the cannula projecting from the housing and being covered by the protective cover.

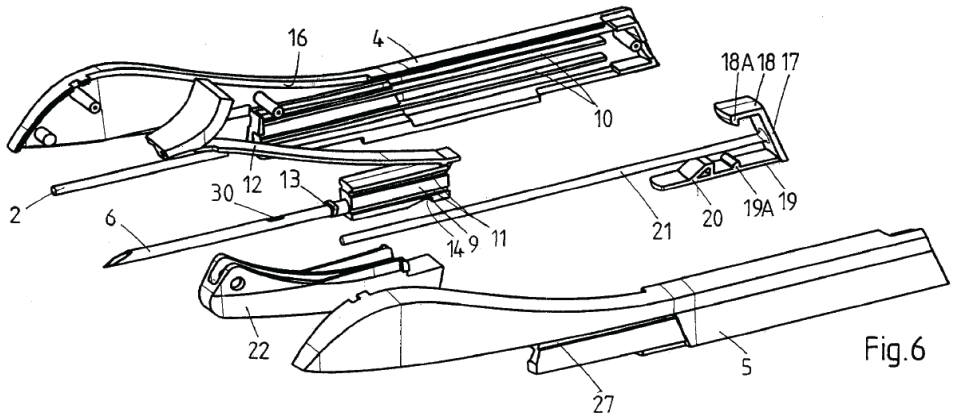

Fig.6

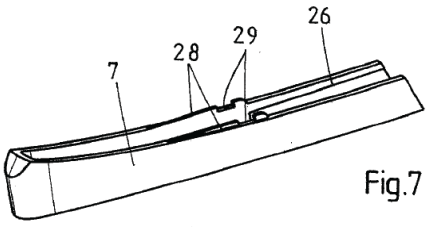

Fig.7

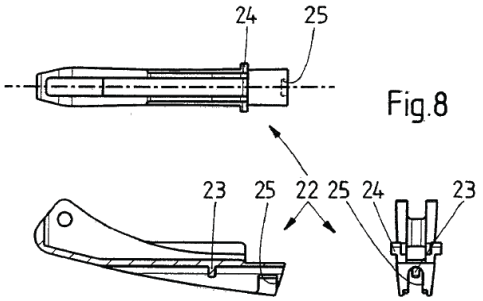

Fig.8

1.2 To deliver the implant, the cover is removed and the cannula is inserted under the skin of the subject by the medical professional holding the housing in one hand (paragraph [0035]). Once the cannula has reached the site where the implant is to be delivered, the cannula is retracted into the housing, for example by pulling on an actuator (visible in Figure 6 but without reference sign) with the index finger of the hand holding the applicator. The retraction of the cannula into the housing causes the rod-like implant to be expelled from the applicator and left in place under the skin. A rod (21) extending into the cannula can facilitate the delivery of the implant by maintaining the longitudinal position of the implant as the cannula is withdrawn.

1.3 To prevent the rod-like implant from becoming dislodged and sliding out of the cannula after the cover has been removed, the claimed applicator includes an automatic mechanism which, at least after the cover has been

removed, secures the implant within the cannula and then disengages it at some point during the insertion of the cannula under the skin or after the insertion has been substantially completed (paragraph [0042]).

As described in paragraphs [0030]-[0035], this mechanism uses a lever (22) arranged inside the housing. This lever is biased towards the cannula in such a way that, as soon as the cover is removed, a protrusion (23) formed on the lever comes into contact with the rod-like implant through a corresponding aperture (30) formed in register in the cannula, thereby gently urging the implant towards the inner wall of the cannula and thus securing it inside the cannula (paragraph [0034]). As the cannula is inserted under the skin, at some point the skin above the cannula will lift the lever to such an extent that the contact between the protrusion and the implant is removed, i.e. the implant is automatically disengaged without requiring any specific action by the medical professional (paragraph [0035]).

With this mechanism, virtually no forces are exerted on the implant not only while the cover is in place, but also while the implant is being expelled from the cannula; only a slight localised pressure is exerted by the protrusion to secure the implant during insertion of the cannula into the skin. This makes the claimed applicator particularly suitable for delicate implants (paragraph [0043]).

2. Sufficiency of disclosure

The appellant submitted that the invention as claimed in auxiliary request 2 was insufficiently disclosed. The Board disagrees. As explained below, a person

skilled in the art would be able to construct the various embodiments of the applicator contemplated by claim 1 without undue burden, using the information contained in the patent description and drawings and common general knowledge.

2.1 The appellant contended that the patent was silent as to how the mechanism disengages the implant "after the cannula has been inserted" into the patient's skin.

As defined in claim 1 and explained in paragraphs [0035] and [0042] of the description, the mechanism for disengaging the implant is based on a lever 22 which is designed to come into contact with the patient's skin at some point during the insertion of the cannula into the patient's skin and, as a result of this contact, to lift the protrusion 23 out of engagement with the implant. It is clear, as the appellant argued, that disengaging the implant necessarily requires the cannula to be advanced into the skin (claim 1: "when the cannula is inserted (...) thereby disengaging the implant").

Therefore, in this context, the claimed feature that the mechanism disengages the implant "after the cannula has been inserted" does not mean that the disengagement takes place some time after the cannula has stopped advancing into the skin, e.g. "after a delay of a few seconds or a few minutes" as asserted by the appellant, but rather, as the Opposition Division considered (page 6, first paragraph of the decision), that it does not occur before the insertion of the cannula has been completed, i.e. only once the whole or a substantial part of the cannula has been inserted under the skin (see paragraph [0042]: "disengage the implant when

insertion of the cannula under the skin of a patient has been substantially completed").

The person skilled in the art would understand from the constructions disclosed in the patent (see, for example, Figures 4 and 10) that the moment at which disengagement occurs depends essentially on the dimensions and geometry of the lever. The Board agrees with the respondent that the person skilled in the art would have no difficulty in designing the lever so that disengagement of the implant occurs when the whole cannula or a substantial part thereof, and not only a limited part of the cannula at its proximal end, has been inserted under the skin.

Moreover, in designing the lever, the person skilled in the art would recognise that the lever must be lifted sufficiently upon contact with the skin so that the protrusion is completely clear of the opening of the cannula or cannula holder, otherwise the cannula could not subsequently be retracted into the housing.

2.2 The appellant did not dispute that the implant could be placed in the cannula holder since the holder is an extension of the cannula. The Board shares this view. However, according to the appellant, the patent would not teach how and where, in that case, the opening could be placed in the cannula holder and how the lever should be designed.

It is true that the mechanisms for disengaging the implant in the two embodiments described in the specification and illustrated in the figures, both of which involve an opening made in the cannula, would not function without modification if the opening were instead located in the cannula holder.

However, the Board agrees with the respondent that the patent provides sufficient guidance to enable a person skilled in the art to adapt without difficulty, *inter alia*, the geometry of the lever, including its protrusion, and that of the cannula holder so as to construct a working mechanism as defined in claim 1.

2.3 The appellant's objection concerning the terms "rotatable" and "pivotable" is not convincing either. The Board shares the Opposition Division's view (page 7, third paragraph of the decision) that, in the context of the patent, these terms are synonymous.

From the patent specification, the person skilled in the art would understand that the lever must have at least the following two properties:
(i) the lever must have at least a first position and a second position in which its protrusion respectively engages and disengages the implant through the corresponding opening provided in the cannula or cannula holder (paragraphs [0034] and [0035]); and
(ii) the lever must be biased towards the cannula or cannula holder (paragraph [0030]) so that, after removal of the cover, it is in the first position in the absence of contact with the skin and it moves to the second position upon sufficient insertion of the cannula into the skin.

The Board agrees with the respondent, as the Opposition Division also concluded (page 8, third paragraph of the decision), that the person skilled in the art would be able to conceive of levers that achieve these two properties and are "rotatable and/or flexible" without undue burden, using their common general knowledge.

3. Added subject-matter

The appellant objected that claim 1 included added subject-matter. The Board disagrees.

3.1 Claim 1 is based on the combination of claims 1 and 4 to 6 as originally filed with additional features taken from the original description, namely that the cannula is "fixed to [the] cannula holder (9), which is slidably received inside the housing (3)" from page 7, lines 10-12, and that "the applicator is configured such that when the cannula is inserted under the skin of a patient, skin on top of the cannula (6) lifts the lever (22) to such an extent that contact between the protrusion (23) and the implant (2) is removed thereby disengaging the implant" from page 10, lines 3-6.

3.2 From the patent application as filed (see especially page 7 of the description, first paragraph), the person skilled in the art would infer that, while the cannula holder must be slidably received in the housing to enable the cannula to be retracted to release the implant, the manner in which the sliding articulation is realised is not important. In particular, the person skilled in the art would understand that it is not limited to the particular sliding mechanism based on the corresponding guides 10 and grooves 11 disclosed on page 7.

Nor does it matter for the sliding articulation that the applicator includes an actuator 8 for retracting the cannula, for example manually. In the original description on page 3, lines 25-26, the retraction of the cannula is mentioned without any reference to an actuator for this purpose.

Therefore, contrary to the appellant's argument, the omission of that particular sliding mechanism and of the actuator 8 from claim 1 does not constitute an inadmissible intermediate generalisation.

3.3 Similarly, although the rod 21 helps to eject the implant from the cannula by maintaining its longitudinal position as the cannula is retracted into the housing (paragraph bridging pages 9 and 10), this rod is not inextricably linked with the other features added to the original claim 1. In particular, this rod was originally defined in a separate dependent claim (original claim 11). Therefore, contrary to the appellant's contention, the omission of the rod from claim 1 does not constitute an inadmissible intermediate generalisation either.

3.4 It is immaterial that claim 1 may cover embodiments in which the sliding of the cannula in the housing or the ejection of the implant from the cannula may be achieved by other means not expressly disclosed in the original application, as argued by the appellant. What is relevant for the purpose of assessing compliance with Article 123(2) EPC is whether claim 1 presents new technical information to the person skilled in the art which was not originally disclosed. As explained above, this is not the case.

4. Inventive step

The appellant raised several inventive-step objections to claim 1 based on D1, D4, D5 and D6. These objections do not convince the Board.

4.1 As acknowledged by the appellant and considered by the Opposition Division (point 14 of the decision), the

applicator of claim 1 differs from those disclosed in D1, D4, D5 and D6 at least by virtue of the specific mechanism for securing the implant inside the cannula or cannula holder and then disengaging it, based on a lever having a protrusion in register with an opening formed in the cannula or cannula holder, the lever being biased towards the cannula/cannula holder such that, in a first position of the lever, the protrusion through the opening urges the implant against the inner wall of the cannula/cannula holder, and wherein the applicator is configured such that, when the cannula is inserted under the skin of the subject, the skin on top of the cannula lifts the lever to a second position so that contact between the protrusion and the implant is removed, thereby disengaging the implant.

Indeed, by contrast, the implant 148 in the applicator of D1 is secured in the cannula 114 by means of a protrusion formed inside the cannula by the cannula itself, namely by a portion 84, 84', 84'' of the cannula which is permanently deformed inwards so as to reduce its internal diameter (Figures 7-10). The protrusion is therefore part of the cannula and moves with it. The pressure exerted by the protrusion on the implant is maintained as long as the implant is inside the cannula and throughout the whole retraction phase of the cannula relative to the implant, until the implant is finally ejected (page 13, lines 5-14).

In D4, the implant 6 is secured inside the cannula 4 by means of a movable thin tailpiece 11 (Figure 1) which is arranged between the inner wall of the cannula and the implant, i.e. inside the cannula (column 5, lines 32-38). Even if the tailpiece is considered as a protrusion that exerts a contact pressure on the implant, it does so from inside the cannula, and not

through an opening in the cannula as defined in claim 1. It is also the sliding movement of the retracting plunger 7 that removes the contact between the protrusion and the implant and releases it.

In D5, the implant 106 - which may indeed be a rod-like implant as claimed, see column 5, lines 51-52 - is secured within a notch 104b, formed in the cannula 104, by means of the outer tube 102 (Figure 4). However, this outer tube has no protrusion that exerts a contact pressure on the implant as claimed. It is also the sliding movement of the retracting outer tube 102 which allows the implant to be released from the notch (column 4, lines 18-20 and 29-32).

In D6, the implant is not secured inside the cannula 240 at all (Figure 3; paragraph [0026]). The benefit of securing the implant inside the cannula is not addressed in D6.

4.2 As explained in paragraphs [0010] and [0035] of the patent specification, the distinguishing features of claim 1 have the technical effect that only a slight localised pressure is exerted by the protrusion to secure the implant during insertion of the cannula into the skin, whereas no forces are exerted on the implant while the implant is being expelled from the cannula.

4.3 The parties disagree on the formulation of the objective technical problem. Even if the problem is formulated as the provision of an alternative applicator for inserting an implant - as suggested by the appellant - the person skilled in the art starting from any one of D1, D4, D5 or D6 and using only their common general knowledge would not have had any motivation, without the benefit of hindsight, to modify

the known applicators to implement therein the above mentioned distinguishing features and thus arrive at an applicator having a mechanism as defined in claim 1.

The fact that locking mechanisms based on a protrusion in register with an opening for engaging a part of the device may be well known from a number of everyday products, as argued by the appellant, does not contradict this conclusion. In the absence of a motivation in that sense, implementing such a mechanism - *a fortiori* where the protrusion is specifically formed on a lever which is lifted by the skin over the cannula as the latter is inserted into the skin - would require substantial modifications to the applicators known from D1, D4, D5 and D6, which go beyond the type of modification which the person skilled in the art would have envisaged without exercising an inventive step.

4.4 The Board also agrees with the respondent, as did the Opposition Division (page 10, penultimate paragraph of the decision), that neither D2 nor D3 disclose or suggest the above mentioned distinguishing features.

In D2 (see Figure 15), it is an O-ring 302, and not a protrusion formed on a lever, which frictionally secures the implant 301 inside the cannula 340 via the opening 303 formed in the latter. Moreover, this O-ring is not intended to be lifted away from the implant in order to release it (paragraph [0072]).

While the penetration guide 7 disclosed in D3 ensures that the cannula is inserted at the correct penetration depth under the skin, this guide is rigid and inflexible (page 6, lines 20-30). It is not intended to

move relative to the cannula, let alone to actuate another part of the applicator.

Consequently, the combination of D1, D4, D5 or D6 with D2 or D3 would not lead the person skilled in the art to the claimed applicator.

4.5 The Board therefore concurs with the respondent that the subject-matter of claim 1 involves an inventive step, as held by the Opposition Division.

5. Conclusion

It follows that none of the appellant's objections prejudice the maintenance of the contested patent on the basis of auxiliary request 2, i.e. in the form found allowable in the decision under appeal. The appeal is therefore to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

K. Boelicke M. Alvazzi Delfrate

Decision electronically authenticated